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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Jennifer K. Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly amended claims 12-15 are directed to a species that is independent or distinct from the invention originally claimed for the following reasons:
This application contains claims directed to the following patentably distinct species of the claimed invention: the species of claim 8 is directed to the embodiment of Figure 4 in which a carrier coating is supplied with the therapeutic and supercritical fluid, together, for coating onto a medical device, whereas the species of claims 12-15 are now directed to an alternative embodiment, as outlined by Applicant's specification, in which a medical device is first coated with a carrier coating, the carrier coating is then swelled with a second, distinct step, and then the swelled carrier coating is contacted with the therapeutic agent and supercritical fluid. Claim 12 as filed with an earlier amendment and examined did not require a separate swelling step, nor did it require any sequence of steps. As originally examined, the coating and exposing and interfacing were allowed generically in any order or simultaneously. The new language renders this species distinct from that of claim 8, previously examined.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.

103(a) of the other invention.

Since applicant has received an action on the merits for the originally presented species of claim 8, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. The rejection of claims 12-15 under 35 U.S.C. 112, first paragraph, has been withdrawn based on Applicant's arguments, withdrawal of these claims, and explanation that the process does not call for the transfer of therapeutic.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-5, 7, 9, 11, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (0 405 284 A2) in view of Benoit et al. (6,087,003). Greiner teaches a method of coating a catheter medical device comprising creating a solution of a pharmaceutical in a supercritical fluid and contacting the mixture to a medical device, wherein a subsequent reduction of pressure transfers the

pharmaceutical from the supercritical fluid to the medical device (abstract; paragraph bridging columns 1 and 2). The solution must inherently be transported to the device to be coated in order to coat the device.

Greiner's method fails to teach the specifics of the delivery of the solution to the medical device for coating. While Examiner notes that the use of pumps, valves, and pipes would have been apparent to one of ordinary skill in the art desiring to transport coating solutions to coating chambers, Examiner cites Benoit, below, to teach these aspects.

Benoit teaches a method of coating medical substrates using a supercritical technology by suspending coating materials in a supercritical fluid by feeding the desired coating material into the autoclave (or R2) as a solute dissolved in a supercritical fluid (col. 10, lines 15-20). As seen in Figure 2 and in column 11, a control valve (V2) is located just prior to entrance into the autoclave (R2). Because Benoit teaches an embodiment which requires the coating material to be interfaced into the supercritical fluid prior to entrance into the autoclave and there are no mixing elements between V2 and R2, Benoit teaches interfacing the coating material to be deposited "with a supercritical fluid upstream of a control valve" and, as seen from the diagram, transporting "within a conduit" as required by newly amended claim 1.

Since Greiner teaches coating a medical device catheter with a pharmaceutical coating material by exposure of said coating material in supercritical fluid and Benoit teaches the various mechanics, such as control valves, conduits, and autoclaves for

accomplishing such a supercritical operation of coating, Benoit would have reasonably suggested the specific means of delivering the supercritical solution of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Benoit in the method of Greiner to provide Greiner with an apparatus capable of handling the supercritical coating operation of Greiner that would be effective and safe for medical and active substances.

Regarding claims 3-4, Greiner teaches immersion of the catheter in the saturated solution, which would qualify as a exposing the catheter to a "bath" of the solution (col. 1, line 55). While Greiner teaches bathing the medical device in the therapeutic solution, he fails to specifically teach spraying of the solution onto the medical device. However, it is Examiner's position that the interchangeability of immersion and spraying as coating techniques is well-known in the art of chemical coating. It would have been obvious to one of ordinary skill in the art to substitute one method for another with the expectation of similar, successful results because both methods are known to provide uniform coatings in a simple manner.

Pump P2 (col. 11, line 19) used in emptying Benoit's autoclave would provide a vacuum force, as required by claims 7 and 21.

Regarding claims 9 and 22 Greiner fails to specifically teach separating the excess therapeutic agent from supercritical fluid.

First, Examiner notes that maintenance of a supercritical fluid at supercritical temperature and pressure inherently requires the use of a coating chamber. Regarding the collection operation, Examiner notes that Greiner's method of immersing a catheter into a solution of a therapeutic agent will not result in attachment of all therapeutic agent that is present in solution to the surface of the catheter. After immersion, excess supercritical fluid, with therapeutic agent dissolved there, will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would collect the excess solution to recover the expensive pharmaceutical agents therein for a subsequent coating operation, as required by the claims.

Regarding claim 11, Greiner teaches a wide variety of catheter substrates to be coated in the method of his invention, including those used in the cardiovascular system, which appear to be "angio-catheters" or those which are inserted peripherally to be used centrally, as required by the claim.

5. Claim 2-3, 8-10, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Benoit as applied to claims 1, 3-5, 7, 9, 11, and 21-22 and further in view of Hossainy (US 6,555,157).

Greiner and Benoit teach that which is disclosed above. Additionally, Greiner teaches the use of supercritical carbon dioxide as the fluid of his invention, as is required by a portion of claim 10. Greiner further teaches the use of such pharmaceutical therapeutic

agents as antibiotics and growth factors (col. 4), among many. However Greiner fails to specifically teach the use of the specific paclitaxel agent required by Applicant in claim 10.

Hossainy teaches the use of antibiotics, growth factors, and paclitaxel, among others, as coatings for implantable medical devices (col. 5, line 51).

Since Greiner in view of Benoit and Hossainy teach the use of therapeutic agents on implantable medical devices and Hossainy teaches the suitability of paclitaxel for such a coating, Hossainy would have reasonably suggested the use of paclitaxel as the therapeutic agent for coating onto the medical device of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Greiner in view of Benoit to coat Greiner's medical device with paclitaxel because it would have been expected that paclitaxel would serve as a beneficial agent when used *in vivo* on a medical device for controlled elution within the vicinity of the implantable device.

As an alternative to the rejection of claim 3 above, Hossainy is cited for teaching that dipping or spraying are commonly used techniques for coating medical devices (col. 2, line 46; col. 3, line 38).

Since Greiner teaches "contacting" the medical device with his solution to create a bath of the solution and Hossainy teaches that contacting can be produced via either spraying or immersion, Hossainy would have reasonably suggested the use of spraying

into the chamber of Greiner in view of Benoit as a means of supplying the coating solution thereto to create the "bath" of Greiner.

As an alternative to the obviousness rejection of claims 9 and 22 above, in which Examiner maintains that recycling of expensive therapeutic agents would have been obvious and immediately envisioned by one of ordinary skill in the art, Examiner cites Hossainy. Hossainy teaches that the therapeutic agents and solvent are collected for recycling to be used to coat subsequent medical devices to avoid wasting the coating agent (col. 3, lines 38-45 and col. 5, line 44). While Hossainy does not specifically state that his solvent and coating material are separated during the recycling operation, it is Examiner's position that when the solvent is a supercritical carbon dioxide fluid, as is required by Greiner, the carbon dioxide would flash off and Examiner cites Subramaniam merely to teach the inherency of the same.

Since Greiner in view of Benoit teach coating medical devices with therapeutic agents and Hossainy teaches avoiding waste of such expensive agents by recycling them, Hossainy would have suggested recycling in the method of Greiner in view of Benoit. It would have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Greiner and Benoit to provide Greiner and Benoit with significant cost savings and reduction of waste by recycling expensive therapeutic agents.

Regarding claim 6, Hossainy teaches that supplying the therapeutic agent as a dispersion or suspension is known in the art in addition to solutions. This appears to meet the limitation of claim 6, however, if a specific size of particle is required by Applicant, Examiner notes that optimization of cause-effective variables would have been obvious to one or ordinary skill in the art. Particle size of a therapeutic agent would affect its rate of dissolution within the body and the timing of its effect.
It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 2 and 8, Hossainy teaches that the coating material of his invention may include, in addition to therapeutic agent in solvent, a polymer substance to "carry" the therapeutic agent on the medical device (col. 5-6, specifically col. 5, line 12). This polymer acts as the "carrier" coating of Applicant. This carrier coating is combined in the solution of therapeutic substance, as required by the species claimed in claim 8. Since Greiner in view of Benoit teach coating medical devices with therapeutic agent and Hossainy teaches the additional use of a carrier coating with such an agent, Hossainy would have reasonably suggested as obvious to one of ordinary skill in the art the use of a carrier component in the method of Greiner in view of Benoit to help firmly adhere the therapeutic agent to the medical device.

Regarding the additional limitations of claim 2, Examiner notes that when viewing the apparatus of Benoit, the therapeutic must be expelled from the conduit prior to transfer to the medical device. Additionally valves, by definition, regulate flow.

Response to Arguments

6. Applicant's arguments filed 3/17/2004 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Technology Center 1700
May 27, 2004